



Used in Lieu of PTO/SB/08A/B
(Based on PTO 04-07 version)

Substitute for form 1449/PTO				Complete if Known	
				Application Number	10/586,107-Conf. #1782
				Filing Date	July 14, 2006
				First Named Inventor	Giampiero De Luca
				Art Unit	1614
				Examiner Name	Not Yet Assigned
Sheet	1	of	3	Attorney Docket Number	30694/39646B

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
A1	US-7,144,577		12-05-2006	Torres	

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)			
B1	WO 00/23097		04-27-2000	Sahltech Goteborg AB	T ⁶

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
	C1	ARIOGLU et al., Efficacy and safety of troglitazone in the treatment of lipodystrophy syndromes, Ann. Intern. Med., 133(4):263-274, 2000.			T ²
	C2	BARBARO et al., An open-label, prospective, observational study of the incidence of coronary artery disease in patients with HIV infection receiving highly active antiretroviral therapy, Clin. Ther., 25(9):2405-2418, 2003.			
	C3	BECKER et al., Isolation and characterization of a sulfoxide and a desamido derivative of biosynthetic human growth hormone, Biotechnol. Appl. Biochem., 10:326-337, 1988.			
	C4	BEWLEY et al., Sequence comparison of human pituitary growth hormone, human chorionic somatomammotropin, and ovine pituitary growth and lactogenic hormones, Int. J. Peptide Protein Res., 4:281-287, 1972.			
	C5	BRINKMAN, Mitochondrial toxicity of nucleoside analogue reverse transcriptase inhibitors, Antiviral Ther., 4(Suppl 2):25 [Abstract 009], 1999.			
	C6	CARR et al., A syndrome of peripheral lipodystrophy hyperlipidaemia and insulin resistance in patients receiving HIV protease inhibitors, AIDS, 12:F51-F58, 1998.			
	C7	CARR et al., An objective lipodystrophy severity grading scale derived from the lipodystrophy case definition score, JAIDS, 33:571-576, 2003.			
	C8	CARR et al., HIV lipodystrophy: risk factors, pathogenesis, diagnosis, and management, AIDS, 17(Suppl 1):S141-S148, 2003.			
	C9	CARR et al., Lipodystrophy associated with an HIV-protease inhibitor, N. Engl. J. Med., 339:1296, 1998.			
	C10	CHEN et al., The human growth hormone locus: nucleotide sequence, biology, and evolution, Genomics, 4:479-497, 1989.			
	C11	DE NOTO et al., Human growth hormone DNA sequence and mRNA structure: possible alternative splicing, Nucleic Acids Res., 9(15):3719-3730, 1981.			
	C12	ENGELSON et al., Effect of recombinant human growth hormone in the treatment of visceral fat accumulation in HIV infection: interim analysis, Antiviral Ther., 4:(Suppl 2):19 [Abstract 006], 1999.			
	C13	ENGELSON et al., Fat distribution in HIV-infected patients reporting truncal enlargement quantified by whole-body magnetic resonance imaging, Am. J. Clin. Nutr., 69:1162-1169, 1999.			
	C14	FRIIS-MOLLER et al., Combination antiretroviral therapy and the risk of myocardial infarction, N. Engl. J. Med., 349(21):1993-2003, 2003.			
	C15	Gertler et al., Inhibition of lactogenic activities of ovine prolactin and human growth hormone (hGH) by a novel form of a modified recombinant hGH, Endocrinol., 118(2):720-726, 1986.			
Examiner Signature		Date Considered			

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /GC/

Substitute for form 1449/PTO				Complete if Known	
				Application Number	10/586,107-Conf. #1782
				Filing Date	July 14, 2006
				First Named Inventor	Giampiero De Luca
				Art Unit	1614
				Examiner Name	Not Yet Assigned
Sheet	2	of	3	Attorney Docket Number	30694/39646B

C16	GHIGO et al., Arginine potentiates but does not restore the blunted growth hormone response to growth hormone-releasing hormone in obesity, <i>Metab.</i> , 41:560-563, 1992.	
C17	GOEDDEL et al., Direct expression in <i>Escherichia coli</i> of a DNA sequence for human growth hormone, <i>Nature</i> , 281:544-548.	
C18	GRAFF et al., Human somatotropin: selective removal with trypsin of residues 135-145 from the hormone molecule with no loss of biological activities, <i>J. Biol. Chem.</i> , 257(5):2365-2369, 1982.	
C19	International Search Report, PCT/EP2005/000758, European Patent Office, 28 April 2005.	
C20	KOTLER et al., Metabolic abnormalities: fat redistribution, glucose metabolism, cardiovascular disease, HIV/AIDS 1999 Annual Update, <i>hiv.medscape.com</i> , 1999.	
C21	KOTLER et al., Studies of body composition and fat distribution in HIV-infected and control subjects, <i>JAIDS</i> , 20:228-237, 1999.	
C22	KRAVCIK, HIV lipodystrophy: a review, <i>HIV Clin. Trials</i> , 1(3):37-50, 2000.	
C23	KRENTZ et al., Anthropometric, metabolic, and immunological effects of recombinant human growth hormone in AIDS and AIDS-related complex, <i>JAIDS</i> , 6:245-251, 1993.	
C24	LEWIS et al., A naturally occurring structural variant of human growth hormone, <i>J. Biol. Chem.</i> , 253(8):2679-2687, 1978.	
C25	LEWIS et al., Altered proteolytic cleavage of human growth hormone as a result of deamidation, <i>J. Biol. Chem.</i> , 256(22):11645-11650, 1981.	
C26	LEWIS et al., Enhancement of the hyperglycemic activity of human growth hormone by enzymatic modification, <i>Endocrinol.</i> , 101(5):1587-1603, 1977.	
C27	LEWIS et al., The 20,000-dalton variant of human growth hormone: location of the amino acid deletions, <i>Biochem. Biophys. Res. Comm.</i> , 92(2):511-516, 1980.	
C28	MARTIAL et al., Human growth hormone: complementary DNA cloning and expression in bacteria, <i>Science</i> , 205(10):602-607, 1979.	
C29	MAUSS et al., Successful treatment of PI-induced visceral abdominal-fat accumulation with R-human growth hormone, <i>AIDS</i> , 12(Suppl 4):145, 1998.	
C30	MERCIE et al., Case report of lipodystrophy observations in patients naïve of protease inhibitor treatment, aquitaine cohort 1999, <i>Antiviral Ther.</i> , 4(Suppl 2):42 [Abstract 018], 1999.	
C31	MILANO et al., Two case reports of unusual lipomatous growths associated with combination antiretroviral therapy, <i>Antiviral Ther.</i> , 4(Suppl 2):56 [Abstract 042], 1999.	
C32	MILLER et al., Visceral abdominal-fat accumulation associated with use of indinavir, <i>Lancet</i> , 351:871-875, 1998.	
C33	REITMAN et al., Lipoatrophy revisited, <i>Trends Endocrinol. Metab.</i> , 11(10):410-416, 2000.	
C34	RIETSCHEL et al., Assessment of growth hormone dynamics in human immunodeficiency virus-related lipodystrophy, <i>JCEM</i> , 86(2):504-510, 2001.	
C35	ROSSINI et al., Metabolic and endocrine studies in a case of lipoatrophic diabetes, <i>Metabolism</i> , 26(6):637-650, 1977.	
C36	SCHAMBELAN et al., Recombinant human growth hormone in patients with HIV-associated wasting: a randomized, placebo-controlled trial, <i>Intern. Med.</i> , 125:873-882, 1996.	
C37	SEIP et al., Generalized lipodystrophy, congenital and acquired (lipoatrophy), <i>Acta Paediatr. Suppl.</i> , 413:2-28, 1996.	
C38	SINGH et al., Modified forms of human growth hormone, <i>Endocrinol.</i> , 94(3):883-891, 1974.	
C39	SKLAR et al., HIV infection and cardiovascular disease - is there really a link?, <i>N. Engl. J. Med.</i> , 349(21):2065-2067, 2003.	
C40	STEIN, Protease inhibitors, coronary disease possibly linked, <i>AIDS Weekly via NewsRx.com</i> (22 November 1999).	
C41	THORLACIUS-UZZING, Zinc in the anterior pituitary of rat: a histochemical and analytical work, <i>Neuroendocrinol.</i> , 45:233-242, 1987.	

Examiner Signature	Date Considered
--------------------	-----------------

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /GC/

Substitute for form 1449/PTO				Complete if Known	
				Application Number	10/586,107-Conf. #1782
				Filing Date	July 14, 2006
				First Named Inventor	Giampiero De Luca
				Art Unit	1614
				Examiner Name	Not Yet Assigned
Sheet	3	of	3	Attorney Docket Number	30694/39646B

	C42	TORRES et al., The effect of recombinant human growth hormone on protease-inhibitor-associated fat maldistribution syndrome [Abstract 675], 6th Conference on Retroviruses and Opportunistic Infections, 1999.	
	C43	TORRES et al., Treatment of dorsocervical fat pads and truncal adiposity with serostim (recombinant human growth hormone) in patients with AIDS maintained on HAART, [Abstract 32164], 12th World AIDS Conference, Geneva, 1998.	
	C44	VELDHUIS et al., Differential impact of age, sex steroid hormones, and obesity on basal versus pulsatile growth hormone secretion in men as assessed in an ultrasensitive chemiluminescence assay, JCEM, 80(11):3209-3222, 1995.	
	C45	VELDHUIS et al., Dual defects in pulsatile growth hormone secretion and clearance subserve the hyposomatotropism of obesity in man, JCEM, 72(1):51-59, 1991.	
	C46	VIGOUROUX et al., Diabetes, insulin resistance and dyslipidaemia in lypodystrophic HIV-infected patients on highly active antiretroviral therapy (HAART), Diabetes Metab., 25:225-232, 1999.	
	C47	WANKE et al., Recombinant human growth hormone improves the fat redistribution syndrome (lipodystrophy) in patients with HIV, AIDS, 13:2099-2103, 1999.	
	C48	WINDISCH et al., Recombinant human growth hormone for AIDS-associated wasting, Ann. Pharmacother., 32:437-445, 1998.	
	C49	Written Opinion of the International Searching Authority, PCT/EP2005/000758, European Patent Office, 28 April 2005.	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	/Gyan Chandra/	Date Considered	03/18/2008
--------------------	----------------	-----------------	------------

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /GC/